Notice of Allowability	Application No.	Applicant(s)	
	10/088,567	AKIRA ET AL.	
	Examiner	Art Unit	
	Anoop Singh	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *6/24/08*.

2. ☒ The allowed claim(s) is/are *35 and 38*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *10/2/08* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632

EXAMINERS' SUPPLEMENTAL AMENDMENT

Claim Status

Applicant's submission filed June 24, 2008 was entered. No claims have been amended, cancelled, or newly added. Claims 35 and 38 are pending in the application.

Claims 35 and 38 stand allowed pursuant to the previous notice of allowance dated August 22, 2008.

An examiner's supplemental amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mike Willis on October 1, 2008.

In the Specification

Replace last paragraph of page 3 through the first paragraph of page 6 with the following paragraphs:

The present invention relates to DNA encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence ("1"), the protein according to "1" wherein a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence is either of the following proteins (a) or (b): (a) a protein comprising the sequence of amino acids shown in Seq. ID No: 2, or (b) a protein comprising a sequence of amino acids wherein one or more of amino acids are deleted, substituted, or added in the sequence of amino acids shown in Seq. ID No: 2, and having reactivity against bacterial DNA having an unmethylated CpG

sequence ("2"), the DNA according to "1" comprising the sequence of bases shown in Seq. ID No: 1 or its complementary sequence, or part or whole of the sequences ("3"), the DNA according to "1" which hybridizes with the DNA comprising a gene according to "3" under a stringent condition ("4"), the protein according to "1" wherein a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence is either of the following proteins (a) or (b): (a) a protein comprising the sequence of amino acids shown in Seq. ID No: 4, or (b) a protein comprising a sequence of amino acids wherein one or more of amino acid are deleted, substituted, or added in the sequence of amino acids shown in Seq. ID No: 4, and having reactivity against bacterial DNA having an unmethylated CpG sequence ("5"), the DNA according to "1" comprising the sequence of bases shown in Seq. ID No: 3 or its complementary sequence, or part or whole of the sequences ("6"), and the DNA according to "1" which hybridizes with the DNA comprising the gene according to "6" under a stringent condition ("7").

The present invention also relates to a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence ("8"), the protein according to "8" comprising the sequence of amino acids shown in Seq. ID No: 2 ("9"), the protein according to "8" comprising a sequence of amino acids wherein one or more of amino acids are deleted, substituted or added in the sequence of amino acids shown in Seq. ID No: 2 ("10"), the protein according to "8" comprising the sequence of amino acids shown in Seq. ID No: 4 ("11"), and the protein according to "8" comprising a sequence of amino acids wherein one or more of amino acids are deleted, substituted or added in the sequence of amino acids shown in Seq. ID No: 4 ("12").

The present invention also relates to a fusion protein comprising the protein according to any one of "8" to "12" fused with a marker protein and/or a peptide tag ("13"), an antibody specifically bound to the protein according to any one of "8" to "12" ("14"), the antibody according to "14" which is a monoclonal antibody ("15"), a

host cell comprising an expression system expressing the protein according to any one of "8" to "12" ("16").

The present invention also relates to a non-human animal wherein a gene encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence is excessively expressed ("17"), a non-human animal wherein a gene function encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence is destroyed on a chromosome ("18"), the non-human animal according to "18" having no reactivity against bacterial DNA having an unmethylated CpG sequence ("19"), the non-human animal according to any one of "17" to "19" characterized in that a rodent animal is a mouse ("20").

The present invention also relates to a method of preparing a cell expressing a protein having reactivity against bacterial DNA having an unmethylated CpG sequence characterized in that the DNA according to any one of "1" to "7" is introduced into a cell wherein a gene function encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence is destroyed on a chromosome ("21"), and a cell expressing a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence obtained by the method of preparing a cell expressing a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence according to "21" ("22").

The present invention also relates to screening method for an agonist or an antagonist of a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence comprising steps of: in vitro culturing a cell expressing a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence in the presence of a target substance, and measuring/evaluating TLR9 activity ("23"), a screening method for an agonist or an antagonist of a receptor protein specifically recognizing bacterial DNA having an unmethylated

CpG sequence comprising steps of: administrating a target substance to a non-human animal wherein a gene function encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence is destroyed on a chromosome, and measuring/evaluating TLR9 activity of macrophages or spleen cells obtained from the non-human animal ("24"), a screening method for an agonist or an antagonist of a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence comprising steps of: administrating a target substance to a non-human animal wherein a gene encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence is excessively expressed, and measuring/evaluating TLR9 activity of macrophages or spleen cells obtained from the non-human animal ("25"), a screening method for an agonist or an antagonist of a protein having reactivity against bacterial DNA having the unmethylated CpG sequence according to either of "24" or "25"using a mouse as a non-human animal ("26").

The present invention also relates to an agonist or an antagonist of a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence obtained by the screening method for an agonist or an antagonist of a receptor protein specifically recognizing bacterial DNA having the unmethylated CpG sequence according to any one of "23" to "26" ("27"), a pharmaceutical composition comprising whole or part of a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence as an active component ("28"), a pharmaceutical composition comprising the agonist or antagonist according to "27" as an active component ("29"), a kit used to diagnose diseases related to the deletion, substitution and/or addition in a sequence of DNA encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence comprising the DNA according to "3", which can compare a sequence of DNA encoding a receptor protein specifically recognizing bacterial DNA having an

unmethylated CpG sequence in a test body with a sequence of bases in the DNA according to "3" ("30").

CONCLUSION

Claims 35 and 38 stand allowed pursuant to the previous notice of allowance dated August 22, 2008.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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